K051220

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SECTION 3. 510(K) SUMMARY

JUN 14 2005

Submitter:	SterilMed, Inc. 11400 73rd Avenue North Minneapolis, MN 55369
Contact Person:	Dr. Bruce Lester VP Research and Development Phone: (888) 856-4870 Fax: (763) 488-3350 blester@sterilmed.com
Date Prepared:	May 11, 2005
Trade Name:	SterilMed Reprocessed Deflectable Electrophysiology Diagnostic Catheters
Classification Name and Number:	Electrode Recording Catheter Class II, 21 CFR 870.1220
Product Code:	NLH
Predicate Device:	SterilMed Reprocessed Deflectable Electrophysiology Diagnostic Catheters (K043513)
Device Description:	The subject device consists of a reprocessed catheter that has a high-torque shaft with a handle at the proximal end, and is steerable. These catheters have an outer diameter of 5F to 7F, a length ranging from 85 to 125 cm, with 4-20 platinum/iridium, radiopaque electrodes along the tip shaft and a variety of inter-electrode spacings and curve styles at the tip. The tip is deflectable. Specific cables, as recommended by the original manufacturer, connect to the handle and interface between the catheter and an external stimulator and/or an electrophysiologic recorder. It should be noted that this submission pertains to the catheter only. It does not include any other components in a system such as, connector cables, external stimulators, or electrophysiologic recorders.
Intended Use:	The SterilMed Reprocessed Electrophysiology Diagnostic Catheters are intended for temporary use during electrophysiology studies for intracardiac sensing, recording, and stimulation. They also provide temporary pacing for the evaluation of cardiac arrhythmias, and are used for electrophysiology mapping of cardiac structures during these evaluations.
Functional and Safety Testing:	Representative samples of reprocessed deflectable electrophysiology diagnostic catheters underwent design testing to demonstrate appropriate functional characteristics, and biocompatibility testing to demonstrate compatibility of the device materials. Process validation testing was done to validate the cleaning, packaging, and sterilization procedures. In

	addition, the manufacturing process includes visual and functional testing of all products produced.
Conclusion:	The new models of deflectable electrophysiology diagnostic catheters reprocessed by SterilMed are substantially equivalent to the models in the original 510(k). This conclusion is based upon the fact that the modified devices have the same fundamental scientific technology and intended use as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 14 2005

SterilMed, Inc.
Bruce Lester, Ph.D.
Vice President Research and Development
11400 73rd Avenue North
Minneapolis, MN 55369

Re: K051220
Trade Name: Sterilmed Reprocessed Deflectable Electrophysiology Diagnostic Catheters
(See Enclosed List)
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: Class II
Product Code: NLH
Dated: May 11, 2005
Received: May 12, 2005

Dear Dr. Lester:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

List of Model numbers

Daig Livewire™ Electrophysiology Catheter			
401938	401606	401578	401581
401939	401933	401579	401917
401940	401934	401583	401582
401941	401575	401584	401904
401990	401915	401585	401905
401991	401923	401586	401914
401600	401926	401587	401908
401603	401576	401588	-
401572	401577	401580	-

EPT Polaris DX™ Steerable Diagnostic Catheter	EPT Polaris DX™ Steerable Diagnostic Catheter Shielded Connector
5570	5570S
5571	5571S
5572	5572S
5573	5573S
5574	5574S
5575	5575S
5576	5576S
5577	5577S
5578	5578S
5579	5579S
9663	9663S
5427	5427S
EPT Polaris X™ Steerable Decapolar Mapping Catheter	
7000D	
7001D	
7003D	
7004D	
7005D	
7006D	
EPT Polaris LE™ Mapping Catheter	**EPT Polaris LE™ Mapping Catheter Shielded Connector**
5590	5590S
5591	5591S
5592	5592S
5593	5593S

5594	5594S
5595	5595S

Bard EP-XT Steerable Catheter	
200769	200771
200770	201009
201116	200740
200737	200738
200735	200739
200898	200736
200525	200794
200526	200795
200527	200796
200741	200797
200772	200798

SECTION 2: INDICATIONS FOR USE

510(k) Number (if known): K051220

Device Name: Reprocessed Deflectable Electrophysiology Diagnostic Catheters

Indications For Use:

The SterilMed Reprocessed Electrophysiological Diagnostic Catheters are intended for temporary use during electrophysiology studies for intracardiac sensing, recording, and stimulation. They also provide temporary pacing for the evaluation of cardiac arrhythmias, and are used for electrophysiology mapping of cardiac structures during these evaluations.

Prescription Use __X____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K051220